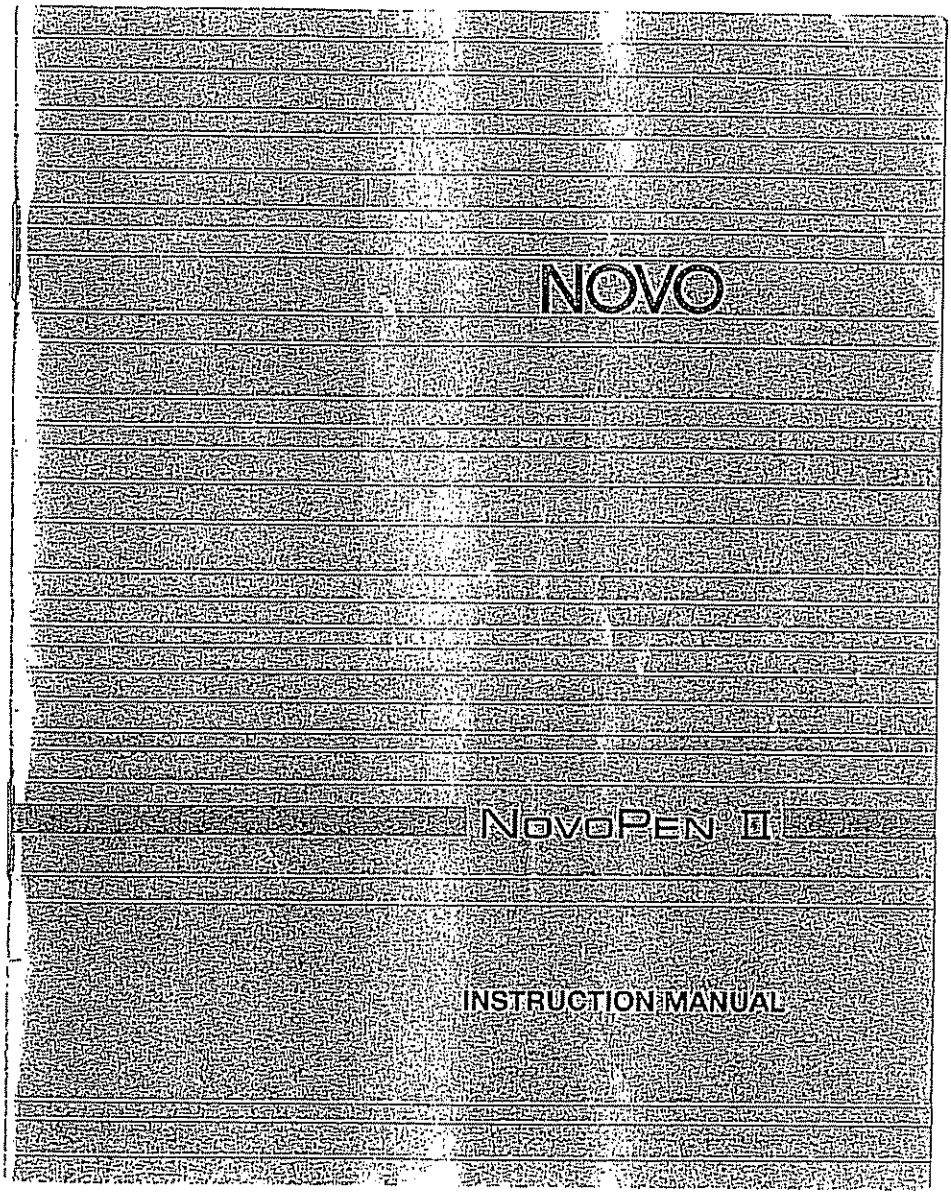
EXHIBIT 22


NOVO
NovoPen II
INSTRUCTION MANUAL

NovoPen® II

Manufactured by:

Hypoguard (UK) Ltd., for
Novo Industri A/S
DK-2880 Bagsvaerd
Denmark

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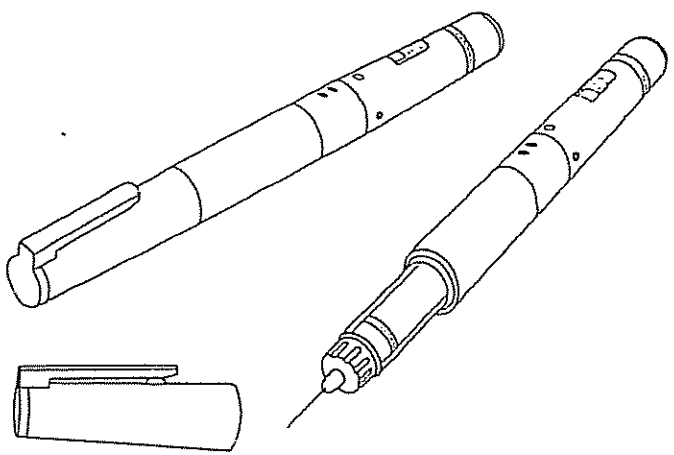
Foxrock, Dublin 18
Tel: Dublin 954211

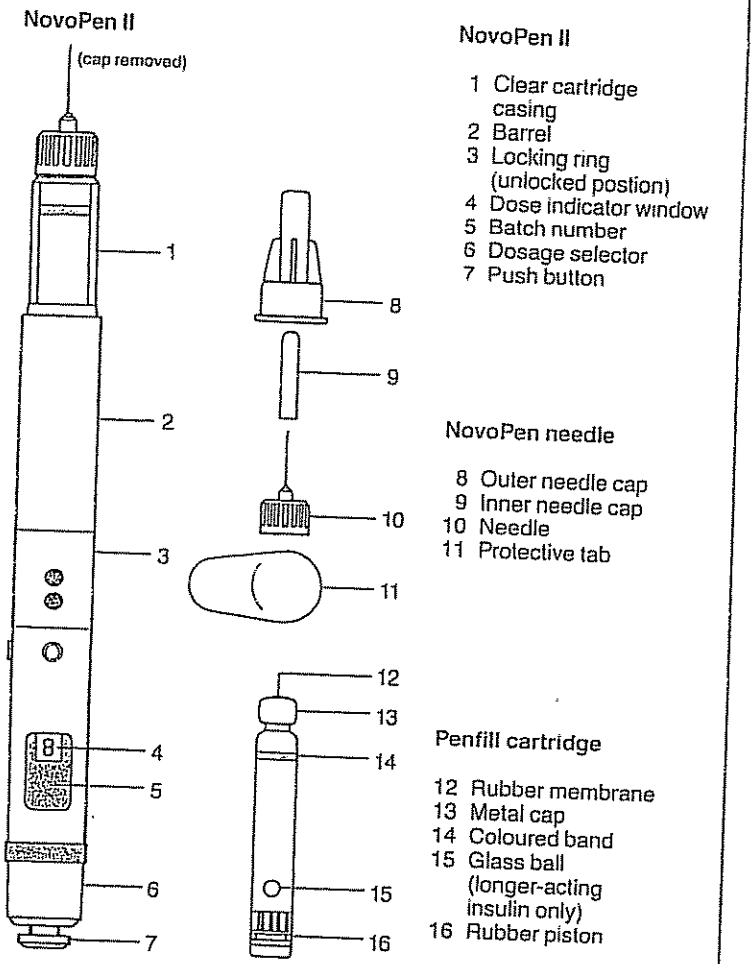
NovoPen® II

NovoPen® II is a dial-a-dose insulin delivery device able to deliver from 2-36 units in increments of 2 units. It must only be used with Novo Penfill® cartridges and NovoPen needles.

Please read these instructions carefully before using your NovoPen II.

Always check that the Penfill cartridge in your NovoPen II contains the correct type of insulin.





NovoPen II

1 Clear cartridge casing
2 Barrel
3 Locking ring (unlocked postion)
4 Dose indicator window
5 Batch number
6 Dosage selector
7 Push button

NovoPen needle

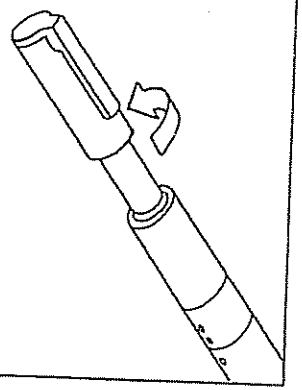
8 Outer needle cap
9 Inner needle cap
10 Needle
11 Protective tab

Penfill cartridge

12 Rubber membrane
13 Metal cap
14 Coloured band
15 Glass ball (longer-acting insulin only)
16 Rubber piston

2

1



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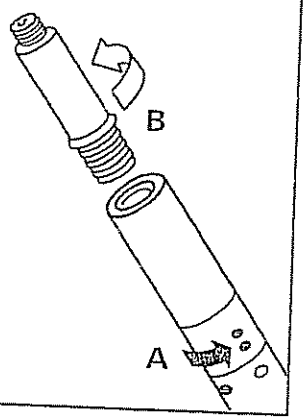


Assembly:

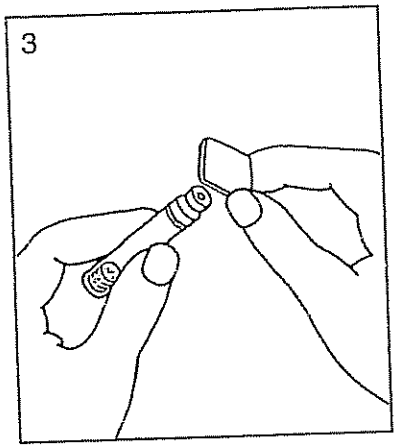
Remove NovoPen II from its case.

Unscrew and remove pen cap.

A Set the locking ring in the unlocked position ●●○, i.e. the 2 closed circles on the locking ring lined up with the open circle on the barrel.

B Unscrew and remove clear cartridge casing.

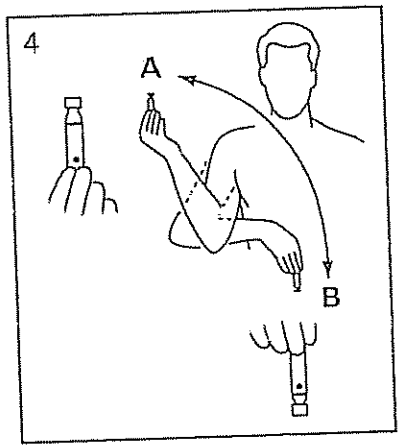
3



(Assembly, cont'd)

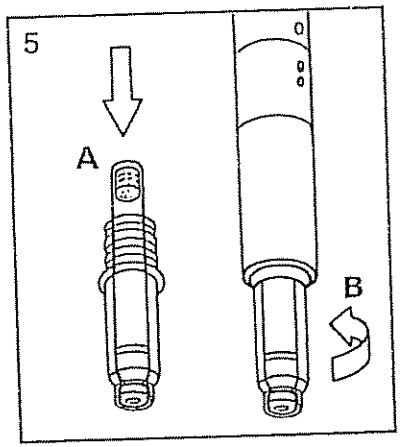
Disinfect the rubber membrane of Penfill cartridge.

If Penfill cartridge contains rapid-acting insulin, proceed as described in fig. 5.



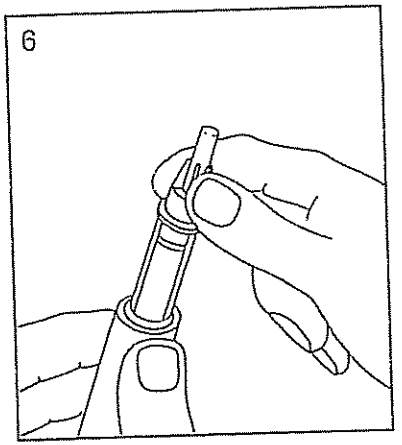
If the Penfill cartridge contains longer-acting insulin, turn cartridge carefully up and down between positions A and B, so the glass ball in the cartridge moves from one end to the other.

Turn it up and down at least 10 times, until the liquid appears uniformly white and cloudy.



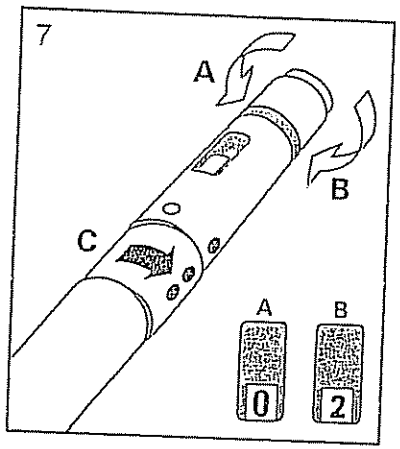
A Insert Penfill cartridge into clear cartridge casing, metal cap first.
Push cartridge until it is fully inserted.

B Lower barrel onto clear cartridge casing and screw firmly home.



Remove protective tab from a NovoPen needle and screw needle firmly onto the pen.

Pull off the outer and inner needle cap.



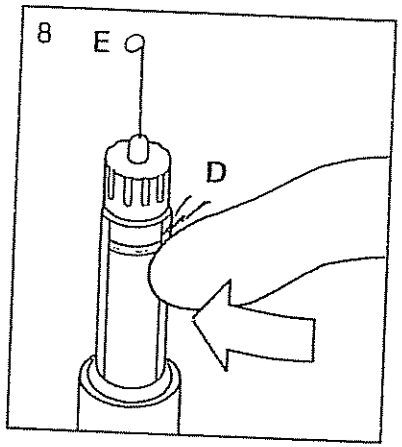
Air shot prior to each injection:

Small amounts of air may collect in the needle and Penfill cartridge during normal use. To avoid the injection of air:

A Set dosage selector to zero in order that the push button mechanism can operate.

B Dial 2 units.

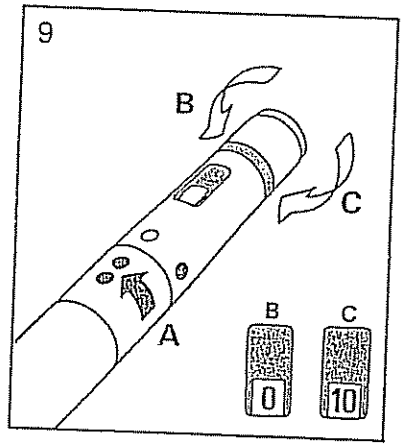
C Twist locking ring a 1/4 turn to the locked position ❶❷❸, i.e. the 2 closed circles on the locking ring lined up with the closed circle on the barrel. Clicking will be heard.



D Hold the pen with the needle upwards and tap the clear cartridge casing gently with the finger a few times.

E Press the push button. A drop of insulin should appear at the needle tip.

If not, return the locking ring to the unlocked position ❶❷○ and repeat procedure as figs. 7-8, until a drop of insulin appears.



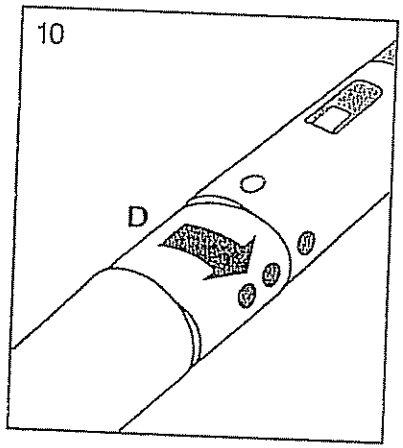
Dosage selection:

A Return locking ring to the unlocked position ❶❷○.

B Set dosage selector to zero.

C Dial the number of units you wish to inject.

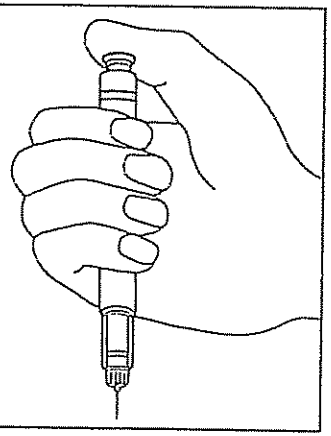
If the wrong number is selected, simply dial the right number.



D Twist locking ring a 1/4 turn to the locked position ❷❸❶. Clicking will be heard.

If you need more than 36 units, two injections will be required.

11



Injection:

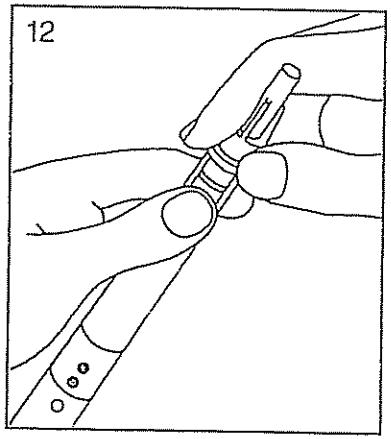
Carry out your injection using the technique advised by your doctor.

Press push button fully down.

If push button is pressed **without** the locking ring in the locked position ❶❷❸, the push button may go down but **no insulin will have been injected.**

If this happens, start again from 9B onwards.

12



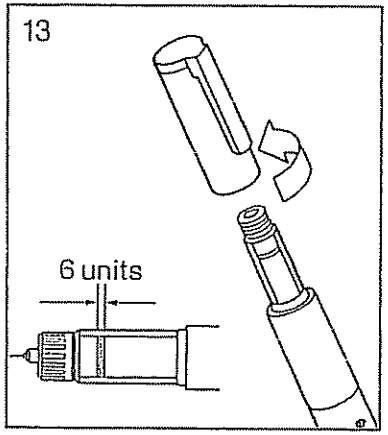
After injection, return locking ring to the unlocked position ❶❷○.

Replace needle caps, hold clear cartridge case firmly and unscrew the needle. Discard it carefully.

Replace pen cap.

Leave the dosage selector untouched, so the number of injected units stays in the window until your next injection.

13



Subsequent injections:

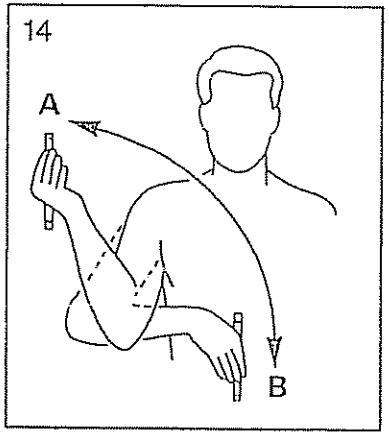
Unscrew and remove pen cap.

Check that NovoPen II contains the insulin type to be injected.

Check that there is sufficient insulin in the cartridge for an injection. The width of the coloured band on the cartridge corresponds to 6 units. Penfill cartridge should be changed if the leading edge of the rubber piston has passed the coloured band.

If Penfill cartridge contains rapid-acting insulin, proceed as figs. 6-12.

14



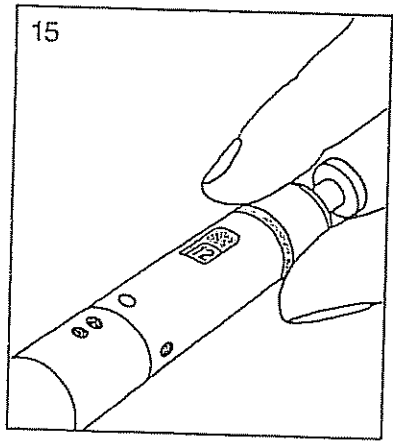
If the Penfill cartridge contains **longer-acting** insulin, turn pen carefully up and down between positions A and B, so the glass ball in the cartridge moves from one end to the other.

Turn pen up and down at least 10 times, until the liquid appears uniformly white and cloudy.

Screw on a new NovoPen needle.

Proceed as figs. 6-12.

15

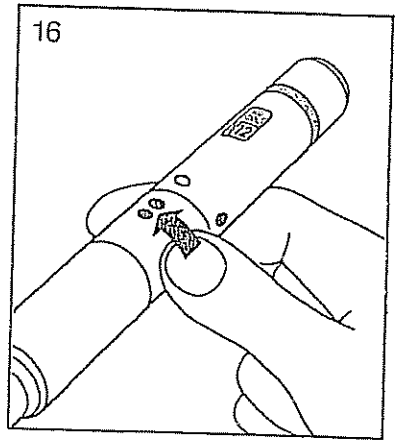


Near-empty Penfill cartridge:

When less than 36 units are left in the cartridge, a dose greater than the number of units remaining cannot be dialled.

The number in the dose indicator window will not advance beyond the number of units remaining, and the dosage selector will slip, if forced further.

16



Change of Penfill cartridge:

Penfill cartridge should be changed when the leading edge of the rubber piston has passed the coloured band (fig. 13).

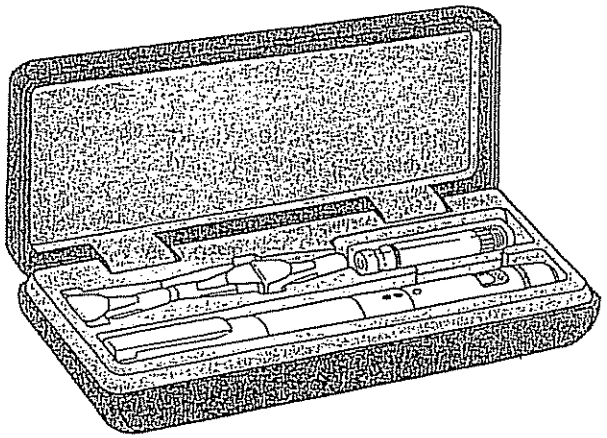
Unscrew clear cartridge casing and remove Penfill cartridge.

Be sure the locking ring is in the unlocked position ⊛⊛○.

Then proceed as in fig. 3 onwards.

Important

- Always screw barrel and clear cartridge casing firmly together.
- Always check before each injection that NovoPen II contains the insulin type to be injected.
- Always expel air, with the NovoPen needle pointing upwards, before each injection (see figs. 7, 8).
- Do not empty the cartridge beyond the coloured band.
- Always check before each injection that the locking ring has been set in the locked position ⊛⊛⊛.
- If longer-acting insulin is used, the needle should be removed immediately after each injection. If the needle is not removed, temperature change can result in some liquid expelled from Penfill cartridge causing a change in the insulin concentration (strength) in Penfill cartridge.
- NovoPen II should be protected against dust and dirt when not carried in its case.
- Keep out of reach of children.



Storage and maintenance of your NovoPen II

Handle your NovoPen II with care as you would with any precision instrument.

Use the carrying case whenever practicable.

Do not expose NovoPen II to situations where there could be a risk of physical damage to the instrument.

A spare Penfill cartridge (in its pack) and three spare NovoPen needles can be kept in the pen case.

Penfill cartridges can be used in the pen or carried with you as spares for a period as explained in the Penfill package insert. Cartridges not in use should be stored in accordance with the directions in the Penfill package insert.

NovoPen II can be cleaned by wiping it with cotton wool moistened with methylated spirit. It should not be soaked in methylated spirit, washed or lubricated as this may damage the mechanism. Dirt and particles should be removed with a soft brush. Even though made of durable materials, the pen must not be exposed to excessive pressure or blows and should be protected against dust and dirt when not carried in its case. Do not try to repair a defective pen.

This pen has been made available free of charge and, in case of defects or breakages, will be replaced provided that the defective pen is returned to your supplier. Novo Industri A/S will assume no responsibility in the case of defects or damages arising from the use of NovoPen II with products other than Penfill cartridges and NovoPen disposable needles.

Always keep a spare syringe and vial of insulin corresponding to your Penfill preparation, in case your pen gets lost or damaged.

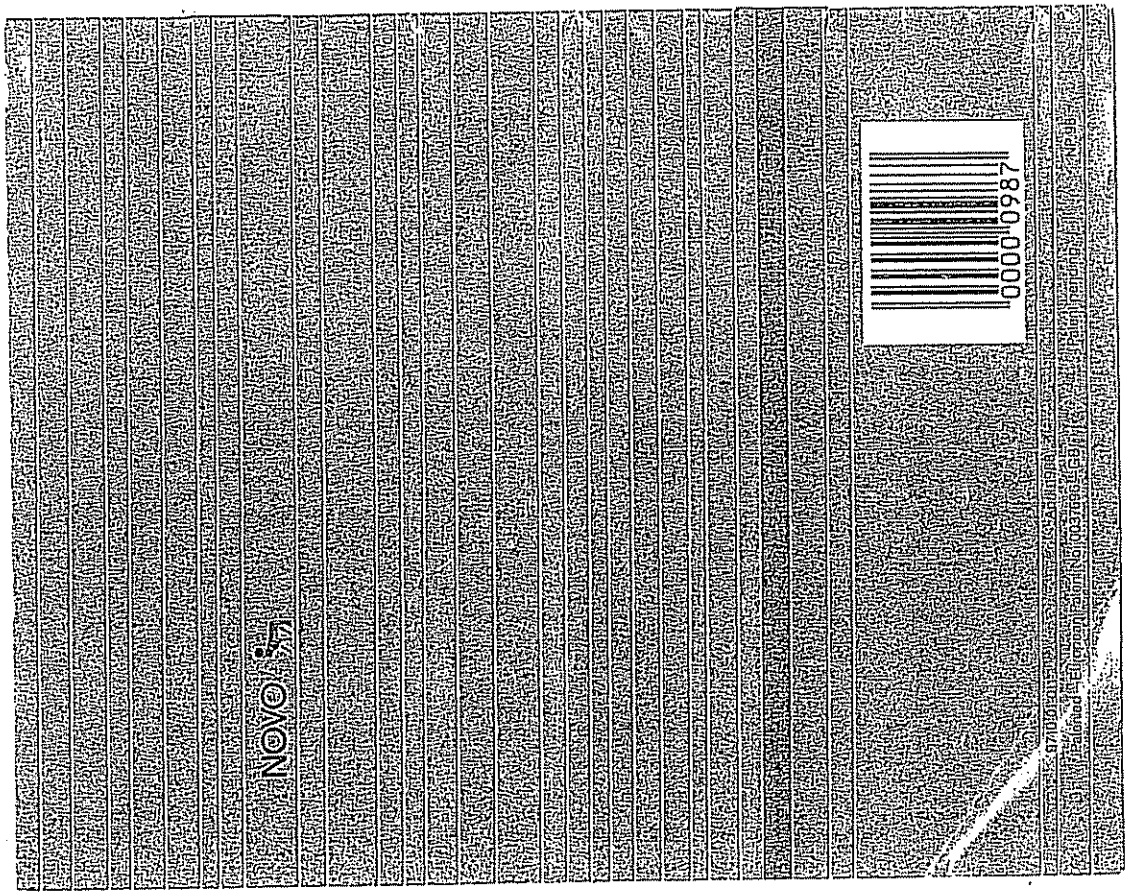

NOVOLEX
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EXHIBIT 23

US005968021A

United States Patent [19]

Ejlersen

[11] Patent Number: 5,968,021

[45] Date of Patent: Oct. 19, 1999

[54] MAGAZINE AND REMOVABLE NEEDLE UNIT

[75] Inventor: Henning Munk Ejlersen, Vedbaek, Denmark

[73] Assignee: Novo Nordisk A/S, Bagsvaerd, Germany

[21] Appl. No.: 08/696,898

[22] PCT Filed: Feb. 27, 1995

[86] PCT No.: PCT/DK95/00085

§ 371 Date: Aug. 22, 1996

§ 102(e) Date: Aug. 22, 1996

[87] PCT Pub. No.: WO95/23005

PCT Pub. Date: Aug. 3, 1995

[30] Foreign Application Priority Data

Feb. 28, 1994 [DK] Denmark 0236/94

[51] Int. Cl.[6] A61M 5/00; B65D 83/10

[52] U.S. Cl. 604/263; 604/192; 604/240; 604/199; 206/365

[58] Field of Search 604/263, 192, 604/232, 199, 110, 111, 194, 239, 240–243, 198, 181, 187; 128/919; 206/363–368, 438, 514

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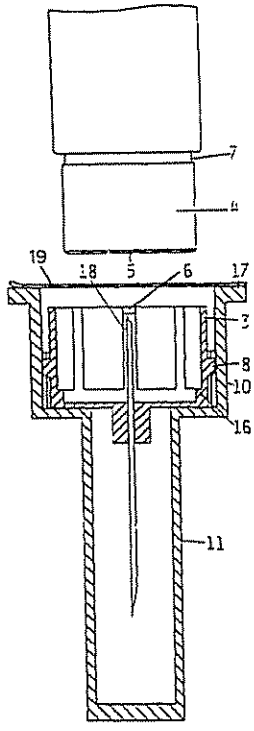
Primary Examiner—Ronald K. Stright, Jr.
Attorney, Agent, or Firm—Steve T. Zelson, Esq.

[57] ABSTRACT

A needle unit comprises a needle mounted in a hub having a sleeve made from a deformable material and surrounding an end of the needle at a radial distance from that needle. The sleeve is designed to be snap-locked onto a connecting piece at the outlet end of a syringe by protrusions on the inner wall of the sleeve engaging a circumferential recess in the outer wall of the connecting piece. It is also designed such that the locking engagement between the protrusions of this sleeve and the recess of the connecting piece is released when certain zones of the outer sleeve wall are pressed inwardly. A magazine for storing the needle unit comprises a compartment which can receive the needle unit in a plurality of rotational positions. The needle unit and magazine include a syringe/needle unit release mechanism which, in a first rotational position, does not press the release zones inwardly, thereby allowing the needle unit to lock onto the syringe, but which in a second rotational position, presses the release zones inwardly so that the needle disengages from the syringe and remains inside the magazine for disposal.

15 Claims, 5 Drawing Sheets



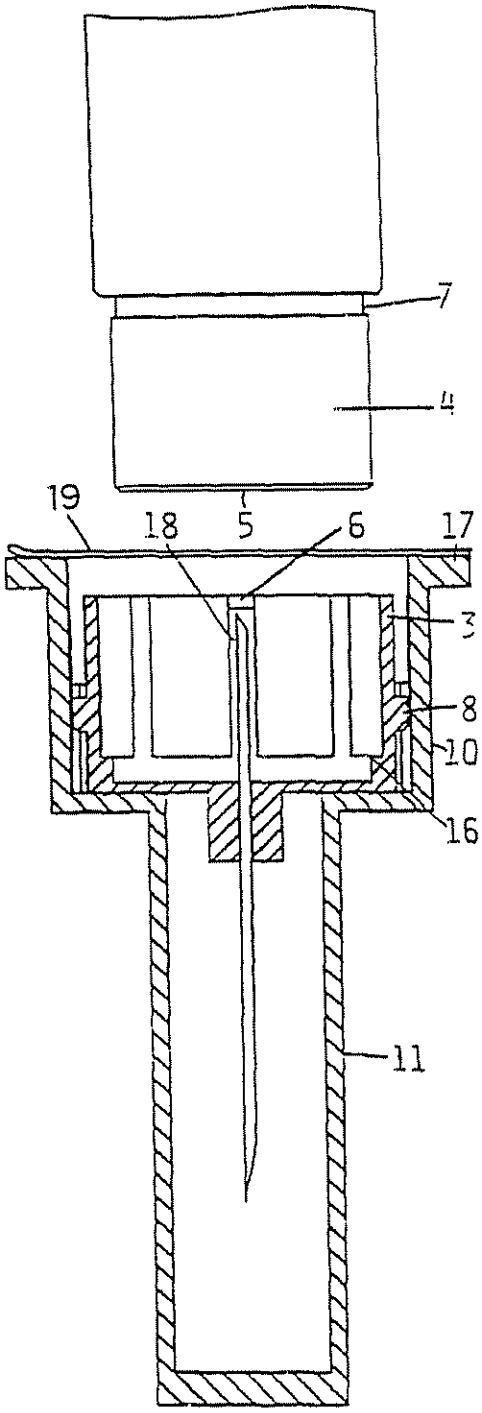


Fig. 1

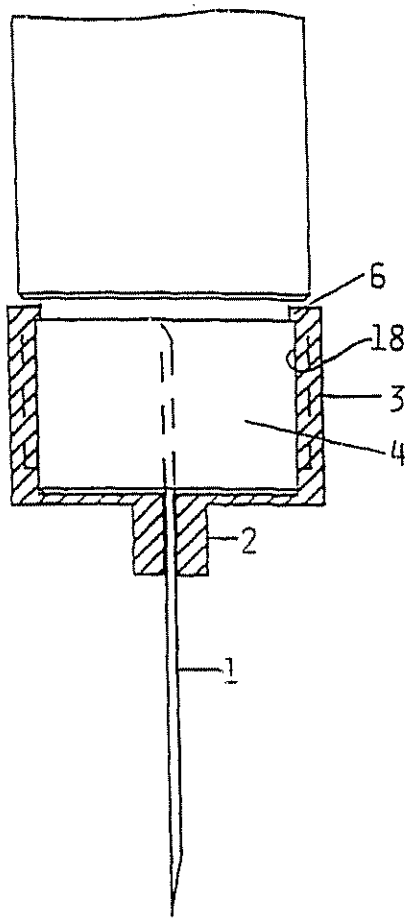


Fig. 2

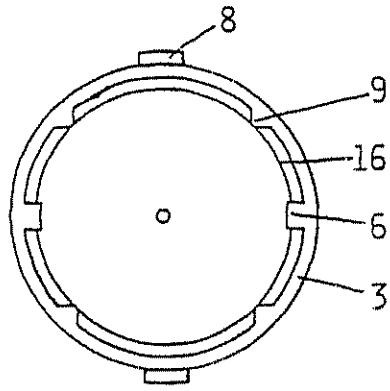


Fig. 3

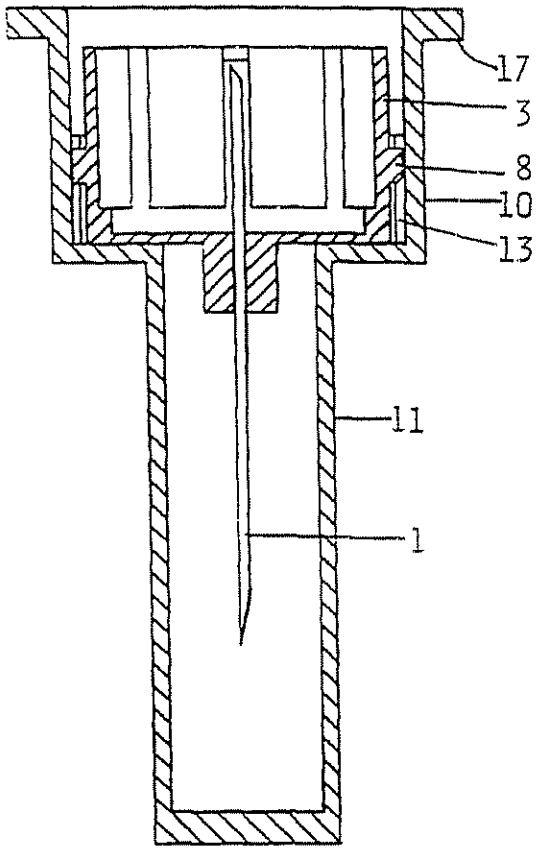


Fig. 4

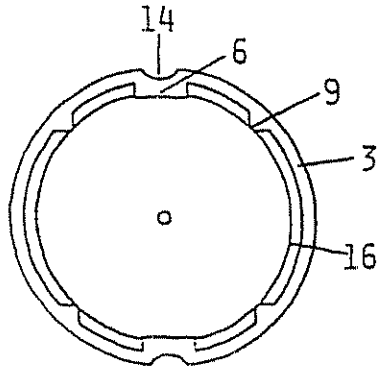


Fig. 6

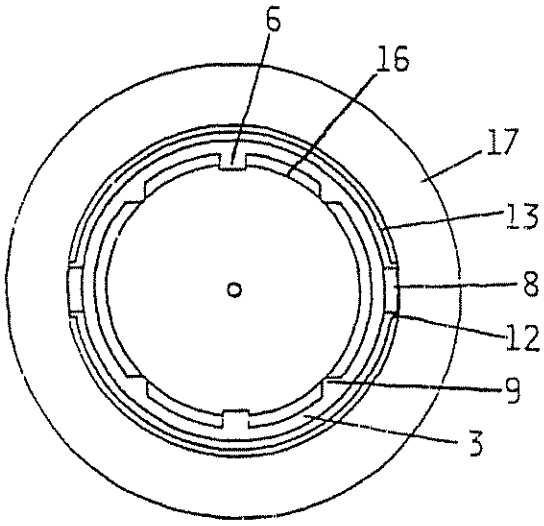


Fig. 5

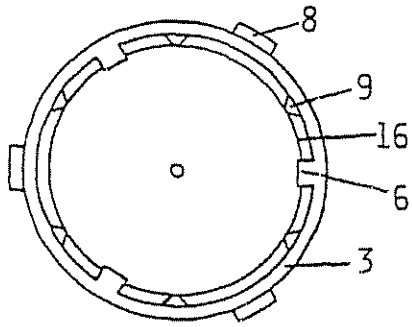


Fig. 9

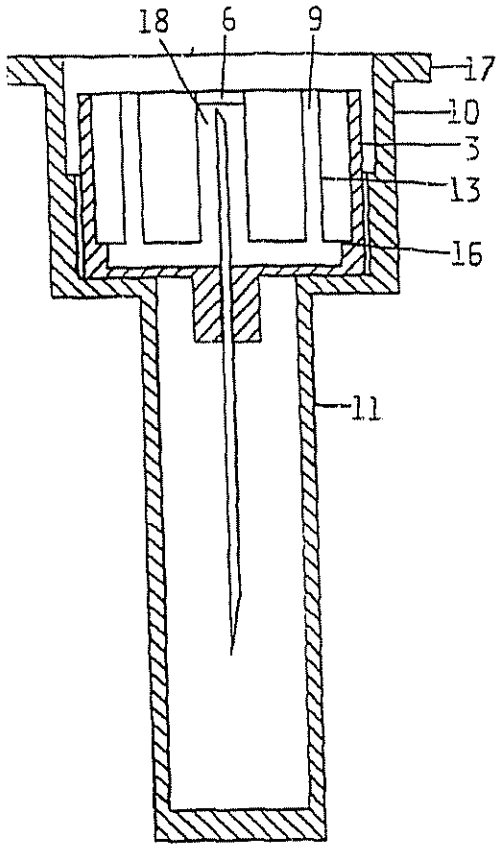


Fig. 7

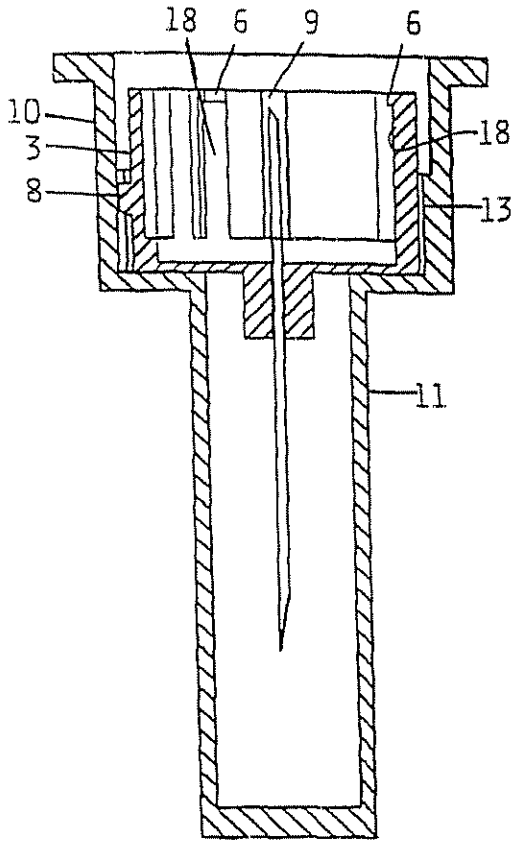


Fig. 10

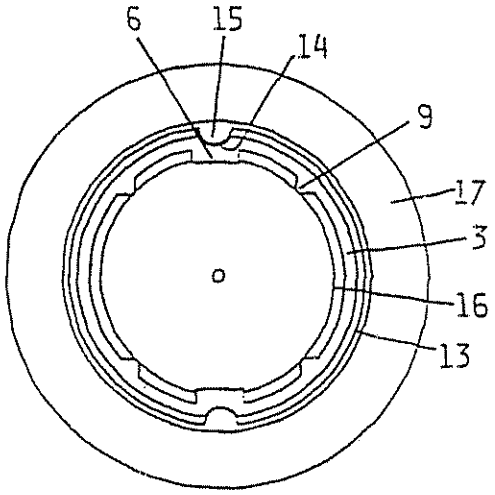


Fig. 8

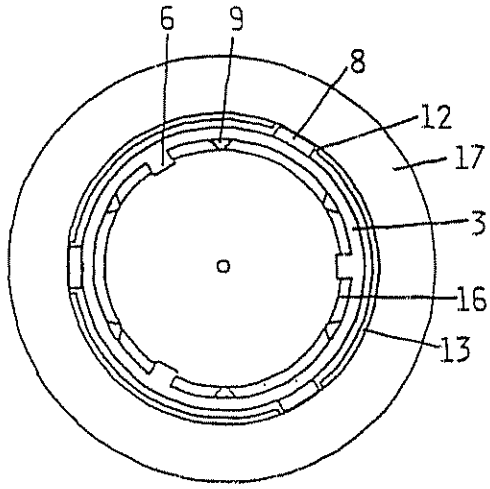


Fig. 11

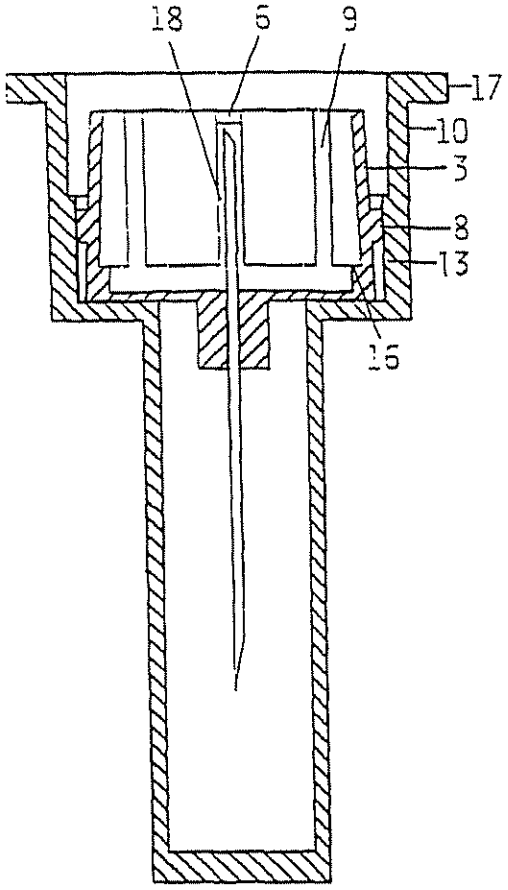


Fig. 12

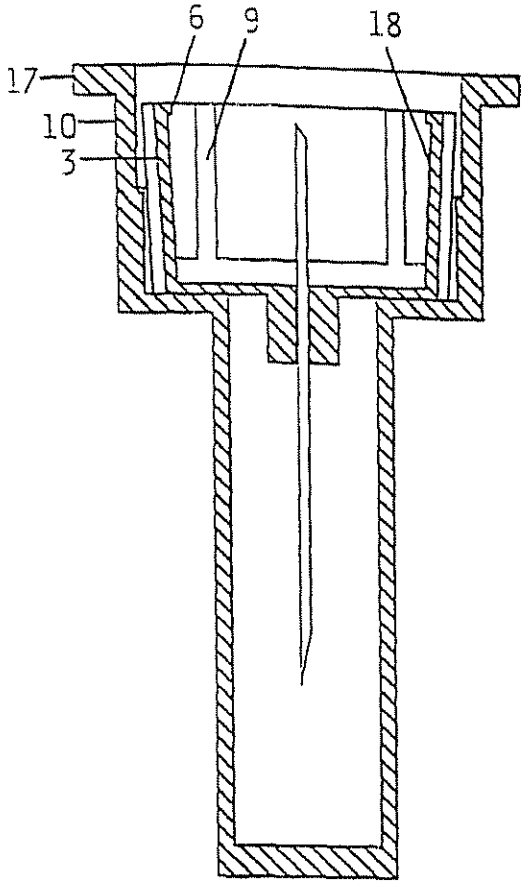


Fig. 14

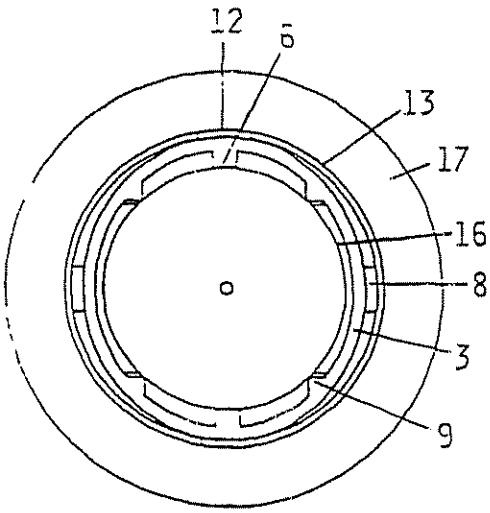


Fig. 13

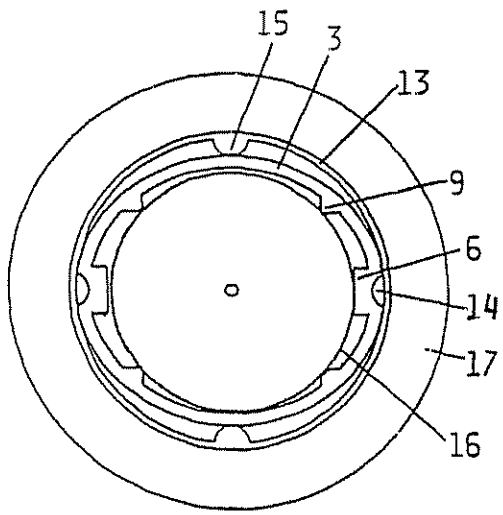


Fig. 15

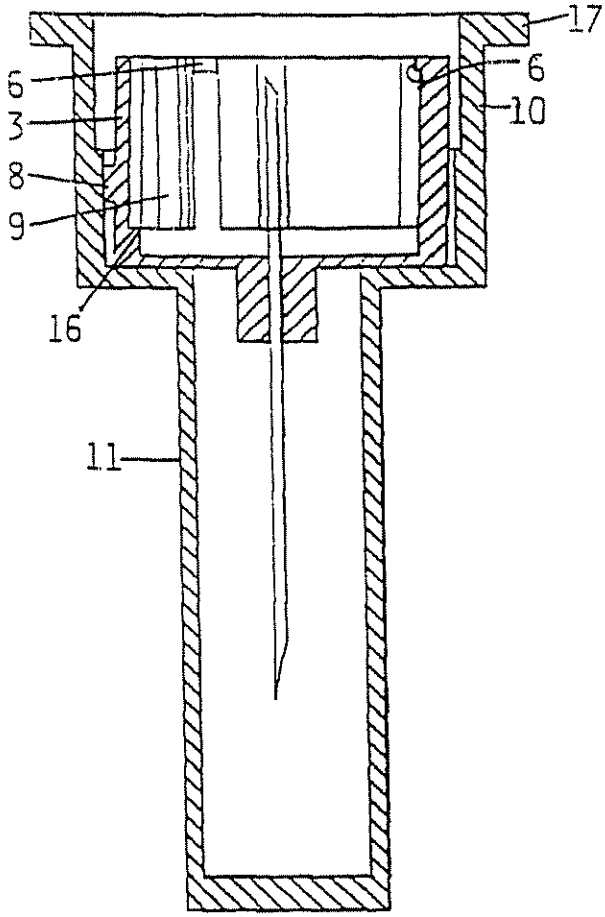


Fig. 16

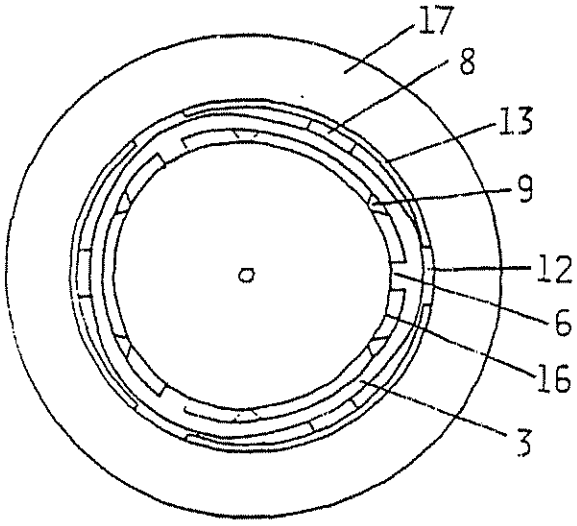


Fig. 17

MAGAZINE AND REMOVABLE NEEDLE UNIT

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a 35 U.S.C. 371 national application of PCT/DK95/00085 filed Feb. 27, 1995, which is incorporated herein by reference.

BACKGROUND OF THE INVENTION

The invention relates to needle units for disposable injection needles, and specifically a needle unit comprising a needle mounted in a hub having a sleeve made from a plastic material and surrounding an end of the needle in a distance from that needle, the unit being designed to be mounted at the outlet end of a syringe having a cylindric connecting piece with a recess in a plane perpendicular to the cylinder axis, which connecting piece is received in the sleeve of the needle unit.

DESCRIPTION OF RELATED ART

By known needle units an inner surface of the depending sleeve is provided with an inner thread corresponding to an outer thread on the connecting piece of the syringe which the unit is intended for. The unit may then be mounted on the syringe simply by screwing it onto the connecting piece of the syringe.

However, such a screwing may be difficult to perform especially to people with reduced tactile motor function, and particularly unscrewing of a used unprotected sharp needle may be difficult if the screw connection has been carefully tightened when the unit was mounted.

Needle units are known of a type which can without screwing be mounted on a syringe which instead of a thread has a circumferential recess at the inner end of its connecting piece. Such needle units have at the inner side of their depending sleeves protrusions engaging the recess of the receiving connecting piece of the syringe. This construction is known from disposable syringes formed by snapping a needle unit onto the neck end of a cylinder ampoule, whereafter the syringe with the needle unit mounted is disposed of after use as a unity, as the needle unit cannot easily be demounted.

SUMMARY OF THE INVENTION

The object of the invention is to provide a needle unit of the snap-on type, which may easily be snapped onto a durable pen type syringe and which may easily be dismounted from the syringe to make it possible to change the needle without having to dispose of the syringe.

This is obtained by a needle unit of the above mentioned type, which unit is characterized in that the sleeve is so designed that the locking engagement between the protrusions of this sleeve and the recesses of the connecting piece is released when radial inward pressures are exerted on specific zones of the sleeve.

In an embodiment of the needle hub at least two protrusions may be provided on the inner surface of the sleeve, the apexes of these protrusions lying on a circle having its centre in the axis of the needle unit and having when the sleeve is not deformed a radius which is smaller than the radius of the connecting piece, and the connecting piece may fit into the sleeve with a play allowing deformation of the sleeve to an extent enlarging the radius of the circle through the apexes of the protrusions to be at least equal to the radius of the connecting piece.

The sleeve may either be deformed when the connecting piece is pressed into the sleeve urging the protrusions to pass over the side wall of this connecting piece until they snap into the recesses in this wall, or the deformation may be obtained by applying a radial inward pressures on the outer side of the sleeve at zones circumferentially displaced from the position of the protrusions. By such radial pressures the sleeve will be deformed so that the protrusions will be drawn out of the recesses in the connecting piece.

To prevent the sleeve from wriggling on the connecting piece due to the play between this sleeve and connecting piece, longitudinal spacer ribs may be provided on the inner surface of the sleeve at positions lying between the protrusions and zones lying halfway between the protrusions, which zones are designed for application of radial inward pressures.

Such spacer ribs are especially indispensable when according to the invention only two protrusions are provided diametrically opposite each other.

In another appropriate embodiment of the invention three protrusions are provided 120° circumferentially spaced. To dismount this needle unit an inward pressure may be exerted at three zones of the periphery of the sleeve, which zones must be circumferentially displaced relative to the points bearing the protrusions.

As the inward protrusions are not visible from the outer side of the sleeve, the positions of the zones for application of radial inward pressures may be indicated on the outer surface of the sleeve. The indication of the zones may appropriately be protrusions on the outer surface of the sleeve. These outward protrusions may serve further purposes as it will be described below.

The invention also concerns a magazine in which the needle unit may be stored. Such a magazine is characterized in that it comprises a compartment conforming the outer contour of the needle unit and having an access opening. The walls of this compartment may be strengthened against deformation and means for cooperation with the zones wherein radial inward pressures shall be exerted to release the hub may be provided.

The means for cooperating with the said zones may be the edge of the access opening of the magazine or of an inner strengthening of the compartment wall, which may be circular with outward recesses for accommodation of outward protrusions at the pressure zones of the sleeve when an unused needle unit is stored in the magazine, whereas engagement between the protrusions at the pressure zones of the needle unit and said edge will provide an inward pressure at said zones, when the unit is inserted in an empty magazine in a rotational position not bringing the outward protrusions on the sleeve into the outward recesses of the access opening or the strengthening of the magazine.

In another embodiment ribs may be provided on an inner cylindric wall of the compartment. In this case the sleeve must be provided with recesses in its outer cylindric wall, which recesses may accommodate said ribs when an unused needle unit is stored in the magazine. These recesses are provided in the outer wall at the positions wherein the inward protrusions of the needle hub sleeve are provided and thereby indirectly indicates the position of the pressure zones as the zones between two recesses. When a needle unit is returned to a magazine in a rotational position wherein the ribs are not accommodated in the recesses, the ribs will exert a pressure on the zones lying between these recesses and will provide the necessary deformation of the sleeve to release the engagement between the inward protrusions of the sleeve and the recesses of the connecting piece of the syringe.

The compartment wall is strengthened to be able to impart the necessary pressure to the zones without being deformed itself. This strengthening may be obtained by the access opening being surrounded by a flange. This flange and the compartment of the magazine may be one integral plastic member.

The flange may appropriately be used as the support for a foil which fixed to the flange covers the access opening and seals the compartment

BRIEF DESCRIPTION OF THE DRAWINGS

In the following a needle unit and a magazine according to the invention will be described in further details with references to the drawing, wherein

FIG. 1 shows a sectional view of a magazine with a needle unit according to the invention and a connecting piece for receiving the unit,

FIG. 2 shows schematically the needle unit in FIG. 1 rotated 90° and mounted on the connecting piece,

FIG. 3 shows the needle unit in FIGS. 1 and 2 seen from the open end of the sleeve,

FIG. 4 shows a sectional side view of the needle unit of FIGS. 1 to 3 stored in a magazine,

FIG 5 shows the magazine with the stored needle unit of FIG. 4 seen from the access end of the magazine,

FIG. 6 shows another embodiment of a needle unit seen from the open end of the sleeve,

FIG. 7 shows a sectional side view of the needle unit of FIG. 6 stored in a magazine,

FIG. 8 shows the magazine of FIG. 7 with the stored unit seen from the open end of the magazine,

FIG. 9 shows still another embodiment of a needle unit seen from the open end of the sleeve,

FIG. 10 shows a sectional side view of the needle unit of FIG. 9 stored in a magazine,

FIG. 11 shows the magazine of FIG. 10 with the stored needle unit seen from the open end of the magazine,

FIG. 12 shows a sectional side view of a magazine with a needle unit according to FIGS. 1–3 finally deposited in the magazine,

FIG. 13 shows the magazine and needle unit of FIG. 12 seen from the access opening of the magazine,

FIG. 14 shows a sectional side view of a magazine with the needle unit of FIG. 6 finally deposited in this magazine,

FIG. 15 shows the magazine of FIG. 14 seen from its open access end,

FIG. 16 shows a sectional side view of a magazine with the needle unit of FIG. 9 finally deposited in this magazine, and

FIG. 17 shows the magazine of FIG. 16 seen from its open access end.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

FIG. 1 shows a needle unit stored in a magazine. The needle unit comprises a needle 1 mounted in a needle hub 2 which has a depending sleeve 3 surrounding an end of the needle 1 in some distance from this needle. The depending sleeve 3 is designed to be received on a cylindric connecting piece 4 of a syringe so that the surrounded part of the needle penetrates a not shown rubber membrane forming at least a part of an end surface 5 of the connecting piece 4.

At two diametrically opposite positions on the inner wall of the sleeve 3 inward protrusions 6 are provided. The protrusions 6 are designed to engage a circumferential recess 7 in the connecting piece 4 receiving the needle.

In FIG. 2 the needle unit has been rotated 90° and the receiving connecting piece 4 has been inserted into the needle unit, and it is shown how the protrusions 6 engage the recesses 7 of the connecting piece. The receiving connecting piece may be a closure part of a cylinder ampoule and the recess may be provided at the neck part of such an ampoule, but here the connecting piece is a part especially designed for cooperation with a needle unit according to the invention.

The needle hub is manufactured of a plastic material which allow some deformation of the sleeve 3 so that the diametrical distance between the apexes of the protrusions 6, which distance is smaller than the diameter of the connecting piece 4 when the sleeve is not deformed, may be increased to allow the inward protrusions 6 to pass over the side wall of the connecting piece 4 until they can snap into the recess 7 when the connecting piece 4 is pressed into the open end of the sleeve 3. During this insertion of the connecting piece 4 the open end of the sleeve 3 is deformed from having a circular appearance into an oval appearance, i.e. when the diameter connecting the inward protrusions is increased the diameter perpendicular thereto will be decreased The not deformed sleeve must be designed to fit over the connecting piece with a play allowing this decrease

To prevent the needle unit from wriggling due to the space between the outer wall of the connecting piece and the inner wall of the sleeve, a number of spacer ribs 9 are provide on the inner wall of the sleeve 3. These ribs will keep the connecting piece 4 centred in the sleeve 3.

In FIG. 3 the needle unit is seen from the open end of the sleeve. The radius of the connecting piece is indicated by a circle 16 which is formed by an edge of a guide at the inner end of the sleeve, into which guide the end of the connecting piece fits. Axial spacer ribs 9 are provided on the inner wall of the sleeve at both sides of the inward protrusions 6 but leaving the zones 90° displaced from the inward protrusions free to be pressed axially inwards until it contacts the wall of the connection piece. As indicated in FIG. 2, ribs 18 are also provided extending longitudinally in the sleeve from the inward protrusions to said guide at the inner end of the sleeve. During the exertion of the radial pressure at the said zones the spacer ribs 9 abut the connecting piece and act as fulcrums assisting the lifting of the inward protrusions 6 out of engagement with the recess 7 of the connecting piece

When it is wanted to dismount the needle unit from the connecting piece, radial inward pressures may by two fingers be imparted on the outer side of the sleeve at said zones to disconnect the snap engagement between the inward protrusions 6 and the recess 7 of the connecting piece. Therefore it is necessary that marks on he outer side of the sleeve indicate the position of such zones or indicate the positions of the inward protrusions.

In the embodiment shown in the FIGS 1–3 such marks are provided as outward protrusions 8 on the outer wall of the sleeve 3. These protrusions have another function which will be described below.

When a new and unused the needle unit is stored in a magazine as shown in FIGS. 4 and 5, the hub with its sleeve is supported in a compartment 10 into which it fits with a play allowing the necessary deformation of the sleeve 3. The inner space of the compartment conforms the outer contour of the hub 2, i.e. longitudinal recesses are provided in the inner wall of the compartment to accommodate the outward protrusions 8 on the sleeve 3. The needle is protected by a needle cap 11 integral with the compartment 10.

To mount a new needle unit on a syringe, the user may grasp the magazine with the unit with one hand without any risk of scratching himself by the needle. With his other hand he may grasp the syringe and insert the connecting piece of this syringe into the open end of the sleeve, the open end of which faces an open access end of the compartment of the magazine. The connection piece 4 is now pressed into the sleeve until the inward protrusions 6 of this sleeve snap into the recess 7 of this connection piece. The needle unit may now be drawn out of the magazine by the syringe.

When a used needle unit shall be disposed of, this needle unit mounted on the syringe is reinserted in the magazine but in a rotational position wherein the outward protrusions 8 of the sleeve 3 are not accommodated in the recesses 12. Thereby the outward protrusions 8 will abut a reinforcement 13 in the compartment and will be pressed radially inwards. As the outward protrusions of the sleeve are provided at the zones at which a radially inward pressure will deform the sleeve in a way bringing the inward protrusions of this sleeve out of engagement with the recesses of the connection piece, the needle unit will be disconnected from the syringe. As the outward protrusions of the sleeve are pressed into the reinforced part of the compartment, the unit will be wedged in this part and will not follow the syringe when it is retracted. A remounting of the needle unit is not possible as the sleeve remains in a deformed condition so that the inward protrusion of the sleeve will not engage the recesses of the connecting part if this part is reinserted in the sleeve. FIGS. 12 and 13 shows the described needle unit wedged into the magazine for final deposition.

To ensure that the sleeve 3 and not the compartment 10 is deformed, when the used needle unit is wedged into this compartment, the compartment wall is reinforced by the provision of the part 13 having an enlarged wall thickness. As another reinforcing feature helping the compartment 10 to keep its cylindric shape, a flange 17 is provided surrounding the access opening of the compartment. The flange 17 may further act as a support for a closure. This closure may be a foil 19 sealed along the flange 17 to enable a sterile storage of the unused needle unit.

FIG. 6 shows another embodiment of a needle unit seen from the open end of the sleeve. This embodiment differs from the one shown in FIG. 6 by the positions of the inward protrusions 6 being indicated by longitudinal grooves 14 in the outer surface of the sleeve 3. FIGS. 7 and 8 shows this unit stored in a magazine having a compartment 10, a needle cap 11, and a flange 17 as has the magazine of FIGS. 4 and 5. The recesses 12 of the magazine of FIGS. 4 and 5 are in FIGS. 7 and 8 replaced by longitudinal ribs 15 which are accommodated in the grooves 14 of the needle unit when this needle unit is new and stored in the magazine. When a used needle unit is reinserted in the magazine it shall be rotated with its grooves 14 displaced 90° from the ribs 15 of the compartment. The ribs 15 will then exert the radial inward pressures on the sleeve 3 which are necessary to disengage the inward protrusions 6 of this sleeve from the recess 7 of the connecting piece. FIGS. 14 and 15 shows a needle unit of the kind just described wedged into its magazine for final deposition.

It shall be noticed that by embodiments wherein the inward pressures are provided by ribs in the compartment, the used needle unit must be reinserted into the compartment in a rotational position by which it is ensured that the ribs acts at the zones designed for being the objects of radially inward pressures. In embodiments using outward protrusions on the sleeve of the needle unit it is inherently ensured that pressures exerted by the protrusions abutting elements in the compartment are exerted at the zones carrying the outward protrusions. The only demand as to the rotational position when reinserted is that this position must differ from the position of the original storage with the outward protrusions accommodated in recesses.

Elements of the FIGS. 6, 7, and 8 which corresponds to the elements of the embodiment described in FIGS. 1–5 are given the same reference numerals.

FIGS. 9, 10, and 11 shows still another embodiment for a needle unit and the magazine for its storage and final deposition wherein three inward protrusions 6 are provided on the sleeve 3 at 120° intervals along the inner periphery thereof. Outward protrusions 8 are provided at the zones where radially inward pressures must be exerted to release the snap engagement between the needle unit and a syringe. Spacer ribs 9 are provided in pairs at both sides of each inward protrusion leaving zones for exertion of radially inward pressures to deform the sleeve. The compartment of the magazine for storage of the new needle unit has three recesses for accommodating the outward protrusions 8 of the needle unit.

In FIGS. 16 and 17 it is shown how a used needle unit of this kind is wedged into the magazine for final deposition.

It appears that the needle unit will always be either mounted on a syringe or stored or disposed of in a magazine.

I claim:

1. In combination a magazine and a removable needle unit,

wherein said needle unit comprises a needle mounted in a hub and a sleeve made from a deformable material surrounding an end of the needle at a distance from said needle, said sleeve including at least one snap-lock element designed to engage a cooperating element on the outlet end of a syringe for securing said needle unit on the syringe, and wherein said sleeve includes specific zones, spaced from said at least one snap-lock member, which when pressed radially inwardly deform said sleeve in a manner such that the locking engagement between said sleeve and the syringe outlet end is released; and

wherein said magazine comprises a compartment for accommodating said needle unit in a plurality of rotational positions; and wherein said needle unit and magazine further include a syringe/needle unit release means which does not press said zones radially inwardly in a first rotational position of said needle unit, such that the needle unit may lock onto a syringe outlet end, and which presses said zones radially inwardly in a second rotational position of said needle unit, thereby causing said needle unit to release from a syringe outlet end.

2. A magazine and needle unit according to claim 1, wherein said syringe/needle unit release means comprises protrusions provided on the needle hub at said zones and a reinforcement part in said magazine which engages said protrusions in said second rotational position to press said zones inwardly, and which includes recesses to receive said protrusions in said first rotational position so as not to press said zones inwardly.

3. A magazine and needle unit according to claim 2, wherein said compartment has an access opening and is reinforced against deformation by a flange surrounding said opening.

4. A magazine and needle unit according to claim 3, wherein said flange and said compartment are one integral plastic member.

5. A magazine and needle unit according to claim 4, further comprising a removable foil fixed to the flange surrounding said opening for sealing said compartment.

6. A magazine and needle unit according to claim 3, further comprising a removable foil fixed to the flange surrounding said opening for sealing said compartment.

7. A magazine and needle unit according to claim 1, wherein said syringe/needle unit release means comprises a plurality of axial ribs on an inner wall of said magazine which press said specific zones inwardly in said second rotational position, and wherein said sleeve includes a plurality of axial recesses for receiving said ribs in said first rotational position so as not to press said zones inwardly.

8. A magazine and needle unit according to claim 7, wherein said compartment has an access opening and is reinforced against deformation by a flange surrounding said opening.

9. A magazine and needle unit according to claim 8, wherein said flange and said compartment are one integral plastic member.

10. A magazine and needle unit according to claim 9, further comprising a removable foil fixed to the flange surrounding said opening for sealing said compartment.

11. A magazine and needle unit according to claim 8, further comprising a removable foil fixed to the flange surrounding said opening for sealing said compartment.

12. A magazine and needle unit according to claim 1, wherein said compartment has an access opening and is reinforced against deformation by a flange surrounding said opening.

13. A magazine and needle unit according to claim 12, wherein said flange and said compartment are one integral plastic member.

14. A magazine and needle unit according to claim 13, further comprising a removable foil fixed to the flange surrounding said opening for sealing said compartment.

15. A magazine and needle unit according to claim 12, further comprising a removable foil fixed to the flange surrounding said opening for sealing said compartment.

* * * * *

EXHIBITS 24 - 26
REDACTED

EXHIBIT 27

IN THE UNITED STATES DISTRICT COURT

IN AND FOR THE DISTRICT OF DELAWARE

- - -

NOVO NORDISK A/S,	:	CIVIL ACTION
Plaintiff	:	
v.	:	
SANOFI-AVENTIS, AVENTIS PHARMACEUTICALS INC., and AVENTIS PHARMA DEUTSCHLAND GMBH,	:	
Defendants	:	NO. 05-645 (SLR)

- - -

Wilmington, Delaware
Wednesday, April 11, 2007
3:00 o'clock p.m.

- - -

BEFORE: HONORABLE SUE L. ROBINSON, Chief Judge

- - -

APPEARANCES:

RICHARDS, LAYTON & FINGER
BY: JEFFREY L. MOYER, ESQ.

-and-

Valerie J. Gunning
Official Court Reporter

been produced. We produced it at a request of theirs in an attempt to be agreeable and to work this out, and what we didn't redact was the portion that dealt with the subject matter of the waiver, which was infringement.

Any other issues in that memo are things that are only between lawyers in the case, either internal to Sanofi-Aventis or outside litigation counsel, and we believe shouldn't be subject to the waiver or discovery.

THE COURT: When I was reading the papers, it wasn't -- okay. So you are saying that Mr. Schwartz was the only decision-maker in this case?

MR. McCARTHY: In this case, because the issue was the company never believed that there was infringement, the decision rested with him, because he decided, well, there are no further issues. Everyone is telling me there's no infringement. So let's move forward and continued making the OptiClik pen.

Stephan Schwartz does have bosses, your Honor, and to be honest with the Court and counsel, we've informed them, we did not search the documents of his bosses. But we have everything going to and from Stephan Schwartz, and we believe that that would have been sufficient to give them the identity of what the decision-maker of the company believed with regard to a status and the opinion of Sanofi-Aventis and whether they infringed or not.

EXHIBITS 28 - 29
REDACTED

EXHIBIT 30

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

SANOFI-AVENTIS U.S. LLC, Plaintiff, v. NOVO NORDISK, INC., Defendant.	CIVIL ACTION NO. 06-1369 (MLC) **O R D E R**

THE PLAINTIFF HAVING MOVED pursuant to Federal Rule of Civil Procedure ("Rule") 65, to preliminarily enjoin the defendant, Novo Nordisk, Inc., from "from disseminating or causing to be disseminated any false representations as to the efficacy, mechanism of action, and side effects of Levemir and Lantus;" and the plaintiff further having moved for an order directing the defendant, inter alia, to (1) "take all steps necessary to secure the return and destruction of all of the false advertising," and (2) "issue corrective advertising to dispel the impact and effect of the false claims previously disseminated;" and the Court having considered the papers submitted in support of and in opposition to the motion; and the Court having heard argument from the parties on April 11, 2006 (dkt. entry nos. 16 & 18); and the Court having issued its preliminary findings and conclusions in a memorandum opinion; and for good cause appearing;

IT IS THEREFORE on this 22nd day of June, 2006, **ORDERED** that the motion for preliminary injunctive relief (dkt. entry no. 5) is **DENIED.**

s/ Mary L. Cooper
MARY L. COOPER
United States District Judge

EXHIBITS 31 - 32
REDACTED

EXHIBIT 33

(D.) Other Information

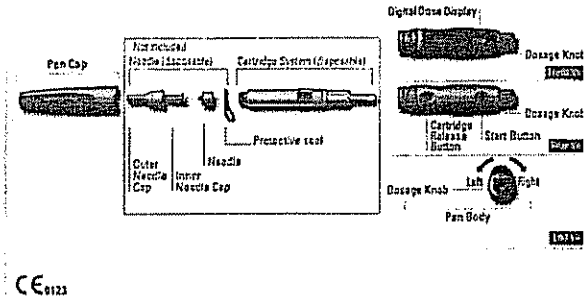
Please read this instruction leaflet carefully and completely before using OptiClik® for the first time. Keep this leaflet for future reference for each time you use OptiClik®.

Talk with your healthcare provider before using OptiClik® about proper injection technique. Before using OptiClik®, your healthcare provider should provide training for the use of the pen or direct you to the appropriate person to get training.

trained person with good vision.

Additional items needed for use with OptiClik®
- Alcohol swabs
- BD Ultra-Fine needles
- 3 mL Lantus or Apidra Cartridge System, at room temperature

If you have any questions about OptiClik® or about diabetes, ask your healthcare professional, go to www.opticlik.com or call Aventis at 1-800-633-1610.



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General Warnings and Precautions

Insulin
Check the label on your Cartridge System to make sure you have the correct insulin before injecting. Using the wrong insulin may result in unwanted changes in blood sugar that could be harmful to your health.

Needles
You must use a new sterile needle (intact protective seal) for each injection. This prevents a blocked needle and air bubbles. In order to avoid injuries, replace Outer Needle Cap before removing and disposing of used needles.

Safety Test
Before each injection, carry out the Safety Test (Step 3): If you do not follow the instructions completely, you may get too much or too little insulin. Injecting too much or too little insulin dose may lead to unwanted blood sugar changes (see the package leaflet for your insulin). Do not perform the safety test without the needle attached.

Damage to OptiClik®
OptiClik® may become damaged by rough handling, dropping, or turning of the Dosage Knob by force. Make sure that no dirt gets in contact with the mechanical parts. You should always make sure that:
a) The Cartridge System is undamaged.
b) The Start Button, Dosage Knob, and Digital Dose Display operate properly.
Do not use tools on OptiClik®. If you are not sure whether or not your OptiClik® is damaged, contact your healthcare professional or call 1-800-633-1610. If damaged, it is no longer safe to use. In an emergency, you can draw up the insulin from the Cartridge System using a U-100 insulin syringe.
OptiClik® should not be used near electrical and electronic equipment.

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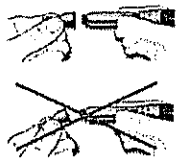
Step 2 Attaching the needle

A Peel off the Protective Seal on the needle.



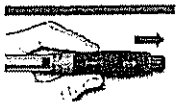
B Use an alcohol swab to wipe the rubber seal on the end of the Cartridge System. Attach a new needle straight to the Cartridge System and screw into place without removing the Outer and Inner Needle Caps.

C Remove Outer Needle Cap from the needle. Save Outer Needle Cap for use later on in discarding the needle.

Step 3 Safety Test

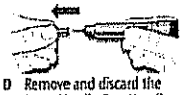
Before each injection, carry out the Safety Test or you may get too much or too little insulin.
Make sure a needle is attached to OptiClik® before you do the Safety Test. Do not press the Cartridge Release Button during these steps.

A Press the Start Button.

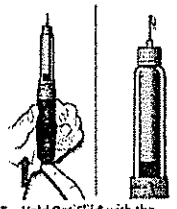


B The Dosage Knob must come out. "80" appears in the Digital Dose Display.

C Turn the Dosage Knob to the right (clockwise) until it clicks. "01" appears in the Digital Dose Display.



D Remove and discard the Inner Needle Cap. Handle the exposed needle carefully.



E Hold OptiClik® with the needle pointing up.
Press the Dosage Knob fully until it stays in.
Insulin must appear at the tip of the needle. If not, repeat the Safety Test. When replacing an empty cartridge system with a new one, it might require repeating this procedure several times. **A Safety Test must be carried out before each injection.**

Additional information about "Cartridge System" and "Removing air bubbles" is on the back side of this leaflet.

Step 4 Setting the dose

A Press the Start Button.

B Turn the Dosage Knob slowly to the right (clockwise) until you reach your required dose. Make sure that the dosage knob is not in between two dosage steps. You must feel and hear a click.

If you have selected a dose that is too high, simply turn the Dosage Knob back (to the left). If you have dialed past 80 units, see (B.) TROUBLESHOOTING, Dose-setting on the back of this leaflet.

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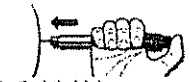
Step 5 Injecting the dose



A Check the label on your cartridge system to make sure you have the correct insulin before injecting. Clean the injection area with alcohol. Insert the needle as recommended by your healthcare professional (e.g., lightly pinch a fold of skin on your upper arm, stomach, or thigh. Insert the needle straight into the pinched skin).

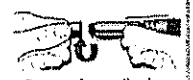
B Press the Dosage Knob slowly and completely. Slowly count to 10 while holding the Dosage Knob in before withdrawing the needle. The Dosage Knob must stay in. The Dosage Knob staying in after injection indicates the delivery of the full dose.

After injecting your dose, the Digital Dose Display will not go back to "0" but will show the delivered dose for 2 minutes. Do not re-inject your dose as this may result in an overdose.

Do not press the Cartridge Release Button or the Start Button while injecting.

Step 6 Removing the needle

A Replace Outer Needle Cap carefully.



B Remove the needle after the injection. For safe disposal of needles see (A.) GENERAL NOTES, Needles for OptiClik® on the back of this leaflet. Always replace Pen Cap on the Pen Body after use.

OptiClik® can be stored with the attached Cartridge System until your next injection. See (C.) STORAGE INSTRUCTIONS.

Step 7 Replacing an empty Cartrid... System

A Make sure the Dosage Knob is pushed in.

B Press the Cartridge Rele... Button, and remove th... entire Cartridge Systen... Dispose of the Cartridge System.

Start again at Step 1 (Inserting the Cartridge System).

PLAINTIFF'S EXHIBIT NO. FOR IDENTIFICATION DATE

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TROUBLESHOOTING

Safety test

No insulin appears at the needle tip during Step F1 (Safety Test):
Repeat Step F1 (Safety Test). If no insulin appears this time either, confirm that:

1. The needle is firmly in position. Replace a blocked or defective needle with a new one.
2. The Dosage Knob has been set correctly (always turn the Dosage Knob to the right/clockwise to preselect the dose).
   Turn the Dosage Knob one click to the right, equal to one unit.
3. The Cartridge System has been inserted correctly. Check by trying to pull the Cartridge System gently out. If the Cartridge System comes out, reinsert it completely, see Step [illegible] (Inserting the Cartridge System). Repeat Step F1 (Safety Test).
4. The Cartridge System is not empty. If it is empty, insert a new one. Repeat Step F1 (Safety Test).

You hear no clicking sound during dose-setting:
The Cartridge System may have been inserted incorrectly. Check by trying to pull the Cartridge System gently out. If the Cartridge System comes out, reinsert it completely, see Step [illegible] (Inserting the Cartridge System). Repeat Step F1 (Safety Test).
If you still hear no clicking sound, try a new Cartridge System and listen for clicking sound. If there is still no clicking sound, obtain a new OptiClik®.

Dose-setting

Insulin drips from the needle tip during dose-setting:
The maximum dose of OptiClik® is 80 units. If you continue to dial after reaching 80 units, insulin will drip from the needle and the display will continue to show "80". In such a case, DO NOT turn back to the required dose, instead dial back (to the left) to "00". Press the Dosage Knob to expel excess insulin and to reset OptiClik®. OptiClik® is now again ready for dose setting. If you need a dose greater than 80 units, you should give it as more than one injection.

You feel resistance during dose-setting and the Dosage Knob will not turn further forward (to the right):
a) You are turning to the left and trying to dial down below zero. Turn the Dosage Knob to the right to dial your dose.
b) The Cartridge System is almost empty and no longer contains a sufficient amount of insulin for the dose you need. For example, if there are only 20 units left in the cartridge and you need 25 units, the dosage knob will stop at 20 units. You can choose to do one of the following:
   1) Do not force the Dosage Knob any further (to the right). Inject the partial dose (20 units in the example), and replace the empty Cartridge System with a new one. Perform the Safety Test as described in Step F1, then inject the remainder of the dose to equal your total prescribed dose. In the above example, the remaining dose is 5 units.
   OR
   2) Dial back (to the left) to "00". Follow Step F2 (Replacing an empty Cartridge System), Step F3 (Inserting the Cartridge System), Step F4 (Attaching the needle), and Step F1 (Safety Test).
c) You have dialed (to the right) past the maximum dose of 80 units and have no needle (or a clogged needle) mounted. Dial completely back (to the left) to "00", and perform Step F4 (Attaching the needle) and Step F1 (Safety Test). Do not force the Dosage Knob to turn further.

The Dosage Knob does not stop at "00":
When turned back completely, the Dosage Knob should stop at "00", however, sometimes it may stop at "02" or "01". Make sure that a needle is attached; then press the Dosage Knob down (insulin will appear at the tip of the needle). OptiClik® is now ready for dose setting.

The Dosage Knob no longer turns after a new Cartridge System has been inserted:
Check that the Cartridge System is firmly clicked in. Reseat the Cartridge System and try again. If it still does not work, try again with a new Cartridge System, see Step [illegible] (Inserting the Cartridge System). Otherwise, get a new OptiClik®.

The Dosage Knob does not come out after you pressed the Start Button:
Do not pull out the Dosage Knob. Check that the Cartridge System is firmly clicked in, see Step [illegible] (Inserting the Cartridge System.

Insulin injection

The Dosage Knob cannot be pressed down for the insulin injection or it does not stay down:
1. In setting the dose, you have turned the Dosage Knob so that it is between two dose steps. Turn the Dosage Knob to the right or the left to the desired dose.
2. The needle may be blocked or defective. Use a new needle.
3. Avoid pushing the Start Button and Dosage Knob at the same time.

After withdrawing the needle from your skin, more than one drop of insulin drips from the needle:
It is possible that you may not have injected your full insulin dose. DO NOT try to make up for the shortfall in your insulin dose by giving a second injection (otherwise you will be at risk for low blood sugar). Please check your blood sugar and consult with your healthcare professional.
You can avoid the problem next time by taking the following steps:
1. Remove any air bubbles that may be present in the Cartridge System (see "GENERAL NOTES: Removing air bubbles").
2. After delivering the insulin dose, slowly count to 10 before withdrawing the needle from your skin.

Cartridge System replacement

The Cartridge System and Pen Body do not click back together properly:
1. Check that the Dosage Knob is pushed in.
2. Check that you have put the Cartridge System correctly into the Pen Body. Take the Cartridge System out and insert it again (see under Step F3 for replacing an empty Cartridge System and Step F3 for inserting the Cartridge System). Repeat Step F4 for attaching the needle and Step F1 for Safety Test.

Digital Dose Display functions

[E1] is displayed:
The Dosage Knob has been forced into the negative range with excessive force. The Cartridge System might be damaged and needs to be replaced. Follow the instructions under Step F3 to replace the Cartridge System and dispose of the damaged Cartridge System. Repeat Step F3 for inserting the Cartridge System, Step F4 for attaching the needle, and Step F1 for Safety Test.

[E2] and [E1] flash alternately:
a) The Dosage Knob has been forced into the negative range and was pushed in. The Cartridge System might be damaged and needs to be replaced. Repeat Step F3 for replacing an empty Cartridge System and dispose of the damaged Cartridge System. Repeat Step F3 for inserting the Cartridge System, Step F4 for attaching the needle, and Step F1 for Safety Test.
b) The Dosage Knob has been turned too quickly. You can choose to do one of the following:
   1) Dispose of the unknown pre-set dose by pressing the Dosage Knob. Set your dose (Step F2) and inject your dose (Step F3). OR
   2) Turn the Dosage Knob slowly backward (to the left) until it stops, and then push the Dosage Knob in. Restart OptiClik® and dial your dose.

No numbers appear on the Digital Dose Display when the Start Button is pressed or when the Dosage Knob is released:
Press the Dosage Knob. Start with a Safety Test (Step F1).
If there are still no numbers on Digital Dose Display, you should obtain a new OptiClik®.

The Digital Dose Display goes blank during dose setting (e.g., if you are interrupted in the middle of your injection preparations):
The energy save function has automatically come into operation. Turn the Dosage Knob one click further (to the right). OptiClik® should now be ready to use again; check the Digital Dose Display and adjust for the right dose if needed.

Battery information

[E3] flashes when the Start Button is pressed:
Your battery is running out. Please obtain a new OptiClik® as soon as possible.

[E4] is displayed when the Start Button is pressed:
Your battery has run out. Please obtain a new OptiClik®.

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STORAGE INSTRUCTIONS

Always store OptiClik® Pen Body at room temperature below 86°F (30°C). Do not store OptiClik®, (with or without the Cartridge System inserted), in a refrigerator at any time. Protect OptiClik® from moisture and direct heat. When OptiClik® is not in use, push the Dosage Knob in to conserve the battery and to ensure OptiClik® functions throughout its expected lifetime.
To avoid dust or dirt from getting into OptiClik®, always replace the Pen Cap.
Once the Cartridge System is used with OptiClik®, the Cartridge System can be used for up to 28 days under normal carrying conditions (for Lantus, below 86°F [30°C]; for Apidra, below 77°F [25°C]). For specific insulin storage information, see "Patient Information" for Lantus® or Apidra® 3 mL Cartridge System.
Do not store OptiClik® with the needle attached to the Cartridge System.

OTHER INFORMATION

Care, cleaning, and maintenance instructio

Handle OptiClik® carefully. To keep it clean, use a clean dan cloth. Clean it once a week. D can impede the operation. DO NOT use cleaning agents. Use alcohol swab only for cleanin the Cartridge System's rubber seal.

Lifetime

OptiClik® has a lifetime of 3 yea See "[A] GENERAL NOTES. How l will OptiClik® last" for details.

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For more information call tol free 1-800-633-1610 or visit www.opticlik.com

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EXHIBIT 34

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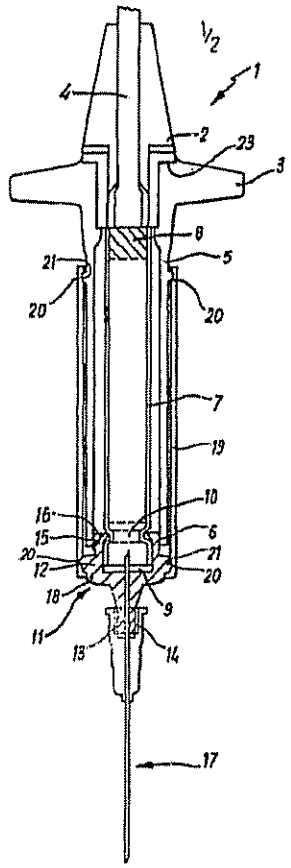
(54) Title: SYRINGES

(57) Abstract

A syringe has a drug-containing cartridge (7) with a bung (8) at one end which is engaged by a plunger (4), and a membrane (9) at its other end which is penetrated by a needle. A connecting structure (11) is connected to (or is formed integrally with) the needle (17) and fits onto the forward end of the cartridge (7) and the syringe. After use the cartridge (7), the connecting structure (11) and the needle (17) can be disposed together. A sleeve (19) is slidably mounted on the structure (11) and can be moved to sheath the needle (17).



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SYRINGES

This invention relates to syringes.

A conventional syringe, e.g. as used by a dentist to administer anaesthetic, has a barrel with a plunger mechanism at one end and a threaded connector for a needle at the opposite end. A drug-containing glass cartridge is inserted into the barrel, the needle is screwed onto the connector so that it penetrates a seal at the forward end of the cartridge, and the plunger mechanism is operated to engage a bung at the rearward end of the cartridge and thereby expel the drug through the needle. After use, the needle and cartridge are removed and discarded.

In order to minimise contamination problems, European Application EP 0394295-A describes a syringe in which, in place of the above mentioned cartridge, there is a drug-containing housing which is attached directly to the needle at one end and to the plunger mechanism at the other end. After use the entire housing, including the needle, is detached from the plunger mechanism and discarded thereby avoiding the need to sterilise the barrel and needle connector of the conventional syringe.

Whilst this arrangement provides an effective solution to contamination problems, it is necessary for the specially-constructed detachable housing to be pre-filled with the drug which can be inconvenient from a manufacturing point of view.

An object of the present invention is to provide a disposable syringe housing which is convenient to manufacture.

According to one aspect of the invention therefore there is provided a detachable housing for a syringe comprising a drug-containing cartridge having a bung at one end and a penetrable member at the other end, the cartridge being adapted for connection to a needle at the said other end, such that the needle penetrates the penetrable member, and being adapted for connection to a plunger mechanism at the said one end, so that the bung can be moved down the cartridge to expel the drug through the needle, characterised in that the cartridge is provided with at least one separate structure attachable relative thereto, said structure being adapted for the said connection of the cartridge to the needle and providing means for releasable connection to the plunger mechanism, whereby the housing comprising the cartridge, the (or each) said structure, and the needle can be detached from the plunger mechanism for disposal together.

With this arrangement the advantages of disposability can be attained with an arrangement which is particularly simple and convenient to manufacture in so far as it involves the use of a simple drug-containing cartridge which may be of the kind used with conventional syringes.

Most preferably there is one said structure which is attachable to the said other end of the cartridge and which is adapted for connection to the needle and which provides the means for connection to the plunger mechanism.

Thus, and in accordance with a second aspect of the present invention there is provided a structure for attachment to a drug-containing

cartridge of a syringe, which cartridge has a bung at a rearward end and a penetrable membrane at a forward end, said structure being adapted for attachment to a needle and having means for attachment relative to the forward end of the cartridge, and means for attachment to a plunger mechanism.

The means for attachment to the cartridge may comprise a clip or constriction or the like which fits around a neck at the forward end of the cartridge, such neck being a feature of conventional cartridges.

The structure may be formed integrally with the needle or alternatively it may incorporate means for connection to the needle which may comprise a threaded boss or nipple.

The means for attachment to the plunger mechanism may comprise an outer peripheral retaining structure, such as a screw-thread, adapted to mate with a corresponding retaining structure at the end of a barrel extension on the plunger mechanism, which extension fits around the cartridge from the rearward to the forward end thereof.

The barrel extension may have a longitudinally movable sleeve which can be moved forwardly to sheath the needle after use. This sleeve may be removable and disposable with the housing.

If desired, provision may be made for aspiration, or slight suck back with the syringe so that it can be seen if a vein or atery has been penetrated, such penetration being revealed by suck back of blood.

Thus, the said structure may be provided with a spring arrangement

which acts to urge the cartridge in a direction away from the needle, in conjunction with a releasable retention device bearing on the top rim of the cartridge. The spring arrangement may comprise a projection engageable with the resilient penetrable member of the cartridge, or an interposed spring means.

The invention will now be described further by way of example only and with reference to the accompanying drawings in which:

Fig. 1 is an axial section of a syringe provided with one form of a disposable housing in accordance with the invention; and

Figs. 2 & 3 are enlarged axial sections of a bottom part of the arrangement of Fig. 1 showing alternative embodiments thereof.

Referring to Fig. 1, the syringe comprises a plunger mechanism 1 (e.g. of stainless steel) having a body part 2 with a finger grip 3, a plunger 4 slidable axially through a bore in the body 2, and a barrel extension 5 coaxial with the plunger 4. The barrel extension 5 may comprise a tube, or apertured tube, or tubular framework.

At its forward end, the tubular extension 5 has an internal screw-thread 6.

A conventional drug-containing cartridge 7 is used with the syringe, such cartridge comprising a glass tube with a bung 8 within one (rearward) end and a foil covered penetrable membrane 9 across the other (forward) end. The glass tube is shaped to provide a circumferential groove 10 defining a neck close to the forward end.

A connection structure 11 is attached to the forward end of the cartridge 7. This structure 11 comprises a plastics body of cup-shaped form with a cylindrical part 12 which is closed at one end and has a central axially projecting boss 13 on its outer face.

There is a narrow axial bore through the closed end and the boss 13. The boss 13 and the cylindrical part 12 both have external screw-threads 14, 15.

The cylindrical part 12 has an open end bounded by an inturned lip 16.

There is sufficient resilience in the lip 16 and/or the associated body of the connection structure 11 to enable the structure to be pushed over the forward end of the cartridge 7 so that the lip 16 springs into, or snap fits with, the groove 10 thereby to retain the structure 11 securely on the end of the cartridge 7.

With the connection structure 11 in position the cartridge 7 can be inserted into the barrel extension 5 and held securely in position by screwing the thread 15 of the cylindrical part 12 into engagement with the screw thread 6 at the end of the barrel extension 5.

A conventional needle 17 can then be screwed on to the boss 13 so that its rear end penetrates the membrane 9.

In this position the rearward end of the cartridge 7 is at the rearward end of the barrel extension 5 and the bung 8 is close to the end of the plunger 4.

The syringe can now be operated in the usual way to cause the bung 8 to be displaced down the cartridge 7 with the plunger 4 to expel drug through the needle 17.

After use, the connection structure 11 is unscrewed from the barrel extension 5 so that the cartridge 7, connection structure 11, and needle 17 can be removed and disposed together.

It will be seen that the cylindrical part 12 of the connection structure 11 has a lower, or forward portion 18 which is not threaded and which remains outside the barrel extension 5 to provide a convenient finger grip for screwing and unscrewing the structure 11. This portion 18 may be enlarged or shaped as desired to further facilitate gripping.

As shown in Fig. 1 a tubular sleeve 19 may be engaged around the connection structure 11, such sleeve 19 being movable axially between a rearward limit position (as shown) at which it overlies the barrel extension 5 and fully exposes the needle 17, and a forward limit position at which it covers the needle 17.

The sleeve 19 is removed and disposed together with cartridge 7 and needle 17 with the sleeve 19 covering the needle 17 to avoid needle stick injuries.

The sleeve 19 has inwardly directed recesses 20 at each end which snap fit with projections 21 on the structure 11 to hold the sleeve 19 in each limit position. Also, the sleeve 19 may be internally longitudinally grooved to accommodate the projections 21 whereby the sleeve 19 is free

to move axially but cannot rotate relative to the structure 11. The rotation of the structure 11 relative to barrel extension 5 can therefore be effected by rotation of the sleeve 19.

With the arrangement described above, full advantages of disposability can be attained using a conventional cartridge.

As shown in the modified embodiment of Fig. 2, the structure 11 has an upstanding small projection 22 which presses against the penetrable membrane 9 at the end of the cartridge. At the top end of the syringe there is a suitable structure (indicated diagrammatically at 23 in Fig. 1) which bears against the top rim of the cartridge and holds the projection 22 pressed firmly into the membrane 9.

If this top end bearing structure 23 is now released, and pressure is released from the plunger 4, the cartridge will move slightly upwards due to the resilience of the membrane 9. This gives a very small suck-back or aspiration effect through the needle.

This is useful e.g. in dentistry where an injection is being made into soft gum tissue and it is desired to avoid penetration of a vein or artery. If penetration of a vein or artery has occurred the aspiration will cause blood to flow back into the cartridge.

Other resilient or spring arrangements may be used to achieve aspiration. Thus, Fig. 3 shows a modification in which the structure 11 is formed integrally with the needle 17. Springy transverse projections 24 or fingers are incorporated for resilient engagement with the bottom of the

cartridge.

It is of course to be understood that the invention is not intended to be restricted to the details of the above embodiment which are described by way of example only.

Thus, for example, the embodiment of Fig. 1 utilises a conventional needle and therefore has said connection structure 11 which is separate from the needle and is adapted to be interconnected thereto by means of the threaded boss 13. However, if desired, and as shown in Fig. 3, the structure 11 may be formed integrally with the needle so that it is supplied together with the needle.

Where the structure 11 is interconnected by means of the threaded boss 13 with a conventional needle, the structure 11 may be supplied with the needle, or ready fitted on the end of the cartridge or as a separate part to be fitted to the needle and to the cartridge prior to use.

The syringe may be as described adapted for end loading of the cartridge. It is however also possible to use a conventional side-loading syringe. The body of the syringe may be formed from plastics or stainless steel or any other suitable material or combination of materials as appropriate.

The interconnection between the structure 11 and the syringe body need not be through screw threads. Especially in the case of a rigid stainless steel syringe body, the interconnection may be achieved in the manner of a push-in or snap-fit or other clip type connection.

Depending on the nature of the syringe and the mode of location of the cartridge therewithin, the structure 11 need not clip around or otherwise connect positively to or even engage the end of the cartridge. The cartridge may be held within the body of the syringe in conventional manner e.g. after side loading thereof through the usual side slot or aperture.

CLAIMS

1. A detachable housing for a syringe comprising a drug-containing cartridge (7) having a bung (8) at one end and a penetrable member (9) at the other end, the cartridge being adapted for connection to a needle (17) at the said other end, such that the needle (17) penetrates the penetrable member (9), and being adapted for connection to a plunger mechanism (1) at the said one end, so that the bung (8) can be moved down the cartridge (7) to expel the drug through the needle (17), characterised in that the cartridge (7) is provided with at least one separate structure (11) attachable relative thereto, said structure (11) being adapted for the said connection of the cartridge (7) to the needle (17) and providing means for releasable connection to the plunger mechanism (1), whereby the housing comprising the cartridge (7), the (or each) said structure (11), and the needle (17) can be detached from the plunger mechanism (1) for disposal together.

2. A housing according to claim 1 characterised in that there is one said structure (11) which is attachable to the said other end of the cartridge (7) and which is adapted for connection to the needle (17) and which provides the means for connection to the plunger mechanism (1).

3. A structure for attachment to a drug-containing cartridge of a syringe, which cartridge (7) has a bung (8) at a rearward end and a penetrable membrane (9) at a forward end, said structure (11) being adapted for attachment to a needle (17) and having means (16) for attachment relative to the forward end of the cartridge, and means (15) for attachment to a

plunger mechanism (1).

4. A structure according to claim 3 characterised in that the means (16) for attachment to the forward end of the cartridge comprises means arranged to fit around a neck at the forward end of the cartridge.

5. A structure according to claim 3 or 4 characterised in that said structure (11) is formed integrally with the needle (17).

6. A structure according to claim 3 or 4 characterised in that said structure (11) is formed separately from the needle and incorporates means (13) for connection thereto.

7. A structure according to any one of claims 3 to 6 characterised in that the means (15) for attachment to the plunger mechanism (1) comprises an outer peripheral retaining structure adapted to mate with a corresponding retaining structure at the end of a barrel extension (5) on the plunger mechanism (1).

8. A structure according to any one of claims 3 to 7 characterised by the provision of a sleeve (19) which is mounted on the structure (11) for longitudinal movement forwardly to sheath the needle (17) after use.

9. A structure according to any one of claims 3 to 8 characterised by the provision of a spring arrangement (22 or 24) on the structure (11) which acts to urge the cartridge in a direction away from the needle (17), a releasable retention device (23) being provided to bear on the top rim of the cartridge to resist said urging of the spring arrangement.

10. A housing according to claim 1 or 2 when using the structure of any

one of claims 3 to 9.

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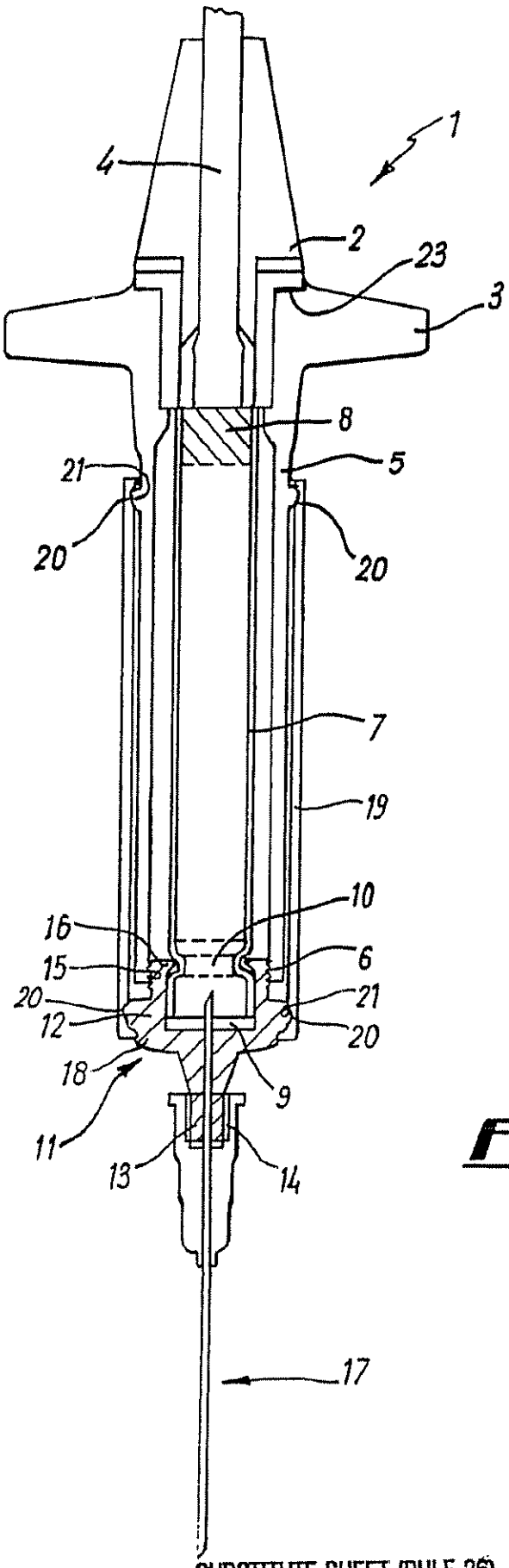

FIG. 1

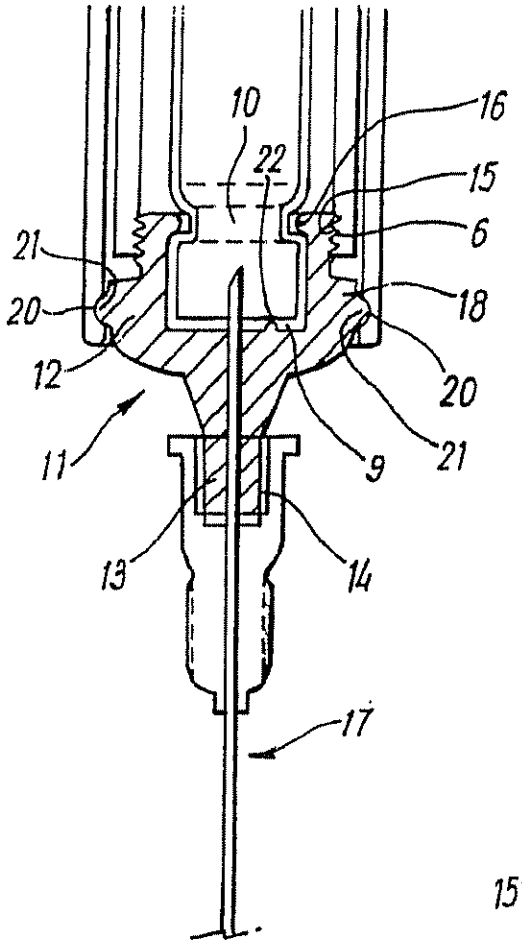
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FIG. 2

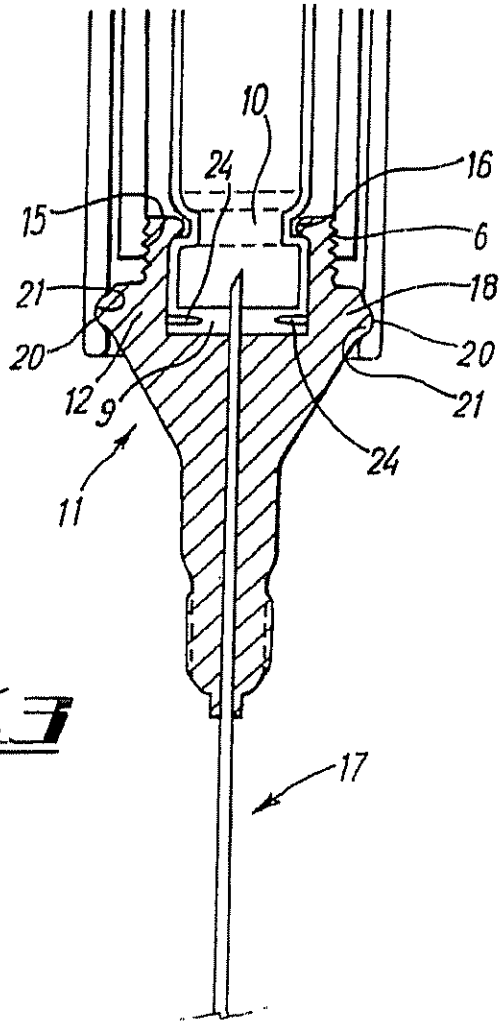
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FIG. 3

INTERNATIONAL SEARCH REPORT

Int: :l Application No
PC /GB 94/02475

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61M5/24

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	US,A,2 778 359 (FRIEDMAN) 22 January 1957 see column 4, line 20 - line 36; figures	1-7,10 8
Y	WO,A,89 04680 (SELDOREN LTD) 1 June 1989 cited in the application see abstract; figures	8
X	US,A,3 825 002 (PAIGE) 23 July 1974 see column 3, line 58 - column 4, line 15; figures	1-7,10
X	US,A,2 671 450 (DANN) 9 March 1954 see the whole document	1-7,10
X	US,A,3 080 866 (FRIEDMAN) 12 March 1963 see column 3, line 57 - column 4, line 9; figures	1-7,10

☐ Further documents are listed in the continuation of box C.

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10 February 1995	09. 03. 95

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Information on patent family members

Internal Application No
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